K072181

12. SMDA Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

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SEP 19 2007

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Date Prepared: August 3, 2007

B. Device Identification

Common Usual Name: Ultraviolet activator for polymerization

Proprietary Name: Mini LED AutoFocus

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
Mini LED and Smartlite Mini	Satelec	K032465	Oct. 21, 2003

The Satelec Mini LED AutoFocus is substantially equivalent to the predicate device by Satelec, Mini LED and Smartlite Mini (K032465) previously cleared by the FDA and currently marketed.

D. Device Description and Intended Use

The Satelec Mini LED AutoFocus is intended to be used by qualified dental practitioners as an ultraviolet activator for polymerizations intended for photo-polymerization in the 420-480 nm waveband of visible light cured (VLC):

- dental materials
- restorative composite materials,
- orthodontic brackets, and orthodontic bonding and sealing materials

The Mini LED AutoFocus is available in two versions, a table top and an OEM (built-in). The table top uses a battery to power the handpiece and a base station

for recharging the battery and storage of the handpiece and battery when not in use.

The OEM version is intended to be built into a chair or cart. A cord connects the handpiece to a power module which is built into the chair. When not in use, the handpiece is placed in a handpiece holder on the chair or cart.

The table top version consists of the following items:

- The Mini LED AutoFocus handpiece with its protective lid, incorporating the Light Emitting Diode and the backlit LCD screen
- The base station for recharging the device incorporating a wattmeter
- The mains adapter
- The Lithium Ion battery
- The sterilizable light guide and the control tip
- The protective light shield
- The user's manual and accompanying documentation.

The OEM version consists of the following items:

- The Mini LED AutoFocus handpiece with its protective lid, incorporating the Light Emitting Diode and the backlit LCD screen
- Power module
- Handpiece cord (allows connection of handpiece to power module)
- The sterilizable light guide and the control tip
- The protective light shield
- The user's manual and accompanying documentation.

E. Substantial Equivalence

Both the Satelec Mini LED AutoFocus and the predicate device, the Satelec Mini LED and Smartlite Mini, are intended to be used by qualified dental practitioners as ultraviolet activators for polymerizations intended for photo-polymerization of visible light cured (VLC) dental materials, restorative composite materials, orthodontic brackets, and orthodontic bonding and sealing materials.

Differences that exist between the devices relating to technical specifications, performances, and intended use are minor and do not affect the safety and effectiveness of the Min LED AutoFocus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SATELEC
C/O Mr. Steve Salesky
Quality Manager
ACTEON, Incorporated
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

SEP 19 2007

Re: K072181
Trade/Device Name: Mini LED AutoFocus
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: August 3, 2007
Received: August 6, 2007

Dear Mr. Salesky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

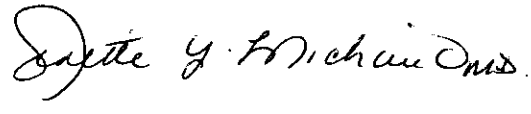
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K072181

Device Name: **Mini LED AutoFocus**

Indications for Use:

The Satelec Mini LED AutoFocus is intended to be used by qualified dental practitioners as an ultraviolet activator for polymerization for:

- photo-polymerization in the 420-480 nm waveband of visible light cured (VLC) dental materials
- photo-polymerization in the 420-480 nm waveband of visible light cured (VLC) restorative composite materials, and
- photo-polymerization in the 420-480 nm waveband of visible light cured (VLC) orthodontic brackets, and orthodontic bonding and sealing materials

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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